UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

PROVIDENCE YAKIMA MEDICAL CENTER, a Washington non-profit corporation; ST. VINCENT HOSPITAL, a Montana non-profit corporation; YAKIMA VALLEY MEMORIAL HOSPITAL, a Washington non-profit corporation; MERLE WEST MEDICAL CENTER, an Oregon non-profit Corporation, and DEACONESS-BILLINGS CLINIC HEALTH SYSTEM, a Montana non-profit corporation,

Plaintiffs,

v.

MICHAEL O. LEAVITT, Secretary, Department of Health and Human Services,

Defendant.

No. CV-03-3096-FVS

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

THIS MATTER came before the Court for a hearing on cross motions for summary judgment. Sanford E. Pitler appeared on behalf of the Plaintiffs. Marcia Berman and Pamela J. DeRusha appeared on behalf of the Defendant.

BACKGROUND

A. Statutory Framework

The Medicare program finances health care services for the elderly, disabled, and individuals suffering from end-state renal failure. 42 U.S.C. § 1395 et seq. The Secretary of Health and Human

Services ("HHS" or "the Agency") administers Medicare through the Centers for Medicare and Medicaid Services ("CMS"), formerly the Health Care Financing Administration ("HCFA"). Medicare contractors referred to as "intermediaries" coordinate Medicare hospital reimbursements.

Until 1986, Medicare reimbursed participating hospitals annually for "reasonable costs" actually incurred in treating Medicare patients. Medicare reimbursed hospitals with residency programs for physicians-in-training, referred to as General Medical Education ("GME") programs, for direct medical payment costs associated with treating Medicare patients. Pls.' Statement of Facts In Support of Summ. J. ¶ 3 ("Ct. Rec. 86").

In 1986, Congress enacted legislation changing the method whereby Medicare reimbursed participating hospitals for GME expenses. The 1986 legislation provided that, effective for cost reporting periods on or after July 1, 1985, payment for GME programs would be calculated by multiplying the number of Full Time Equivalent residents ("FTE") by the number of Medicare patients the hospital treated and the hospital's per-resident amount ("PRA"). CMS would determine the PRA for each hospital by dividing the hospital's total allowable medicare costs for the 1984 cost-reporting period by the number of residents it had in 1984. 1984 thus served as the "base year" for all hospitals. The PRA for subsequent years was determined by adjusting the base year PRA for inflation. For hospitals that did not have a GME program in 1984, Congress provided that CMS should "provide for such approved FTE resident amounts as the Secretary determines to be appropriate, based

on approved FTE resident amounts for comparable programs." 42 U.S.C. § 1395ww(h)(2).

B. Regulatory Framework

HHS finalized a regulation implementing the 1986 legislation in 1989. 54 Fed. Reg. 40286 (Sep. 29, 1989). 42 C.F.R. 413.86(e)(4)(I)[1] ("the 1989 regulation") provided that CMS would assign PRAs to hospitals' with GME programs established after 1984 based on the lower of two amounts, either the hospital's actual costs during the first

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[1] The 1989 regulation provided, in pertinent part,

> (4) Exceptions -- (I) Base period for certain hospitals. If a hospital did not have any approved medical residency training programs or did not participate in Medicare during the base period, but either condition changes in a cost reporting period beginning on or after July 1, 1985, the intermediary establishes a per resident amount for the hospital using the information from the first cost reporting period during which the hospital participates in Medicare and the residents are on duty during the first month of that period. Any graduate medical education program costs incurred by the hospital before that cost reporting period are reimbursed on a reasonable cost basis. The per resident amount is based on the lower of the following:
>
> > (A) The hospital's actual costs, incurred in connection with the graduate medical education program for the hospital's first cost reporting period in which residents were on duty during the first month of the cost reporting period.
> >
> > (B) The mean value of per resident amounts of hospitals located in the same geographic wage area, as that term is used in the prospective payment system under Part 412 of this chapter, for cost reporting periods beginning in the same fiscal years. If there are fewer than three amounts that can be used to calculate the mean value, the intermediary must contact HCFA Central Office for a determination of the appropriate amount to use.

42 C.F.R.42 413.86(e)(4)(I)

cost reporting period during which it had residents on duty or the mean of the PRAs of all other hospitals in the same geographic wage area.[2] 42 C.F.R. § 413.86(e)(4)(I). HHS explained its rationale for using geographic wage area as a proxy for comparability:

> We believe that, since the major component of direct GME costs is the salaries of residents and teaching physicians, it is appropriate to use the geographic wage area classifications as used by the Medicare prospective payment system as a guide in making these determinations. However, the amounts paid to the hospitals for new GME programs should bear some relationship to the actual costs of the program, especially the first year's costs.

53 Fed. Reg. 40286, 40290 (Sept. 29, 1989).

When a hospital was located in a geographic wage area with less than three teaching hospitals, the regulation provided that CMS should contact CMS's Central Office for a determination of the hospital's PRA rather than relying on either of the foregoing criteria. 42 C.F.R. § 413.86(e)(4)(i)(B). The administrative record for 42 C.F.R. § 413.86 contains no additional discussion of hospitals located in areas with less than three teaching hospitals.

Between 1989 and 1997, CMS was asked to determine PRAs for between six and twelve hospitals located in areas with less than three teaching hospitals that had established GME programs after 1984. In each of these cases, the Central Office directed the relevant intermediary to determine the PRA using a method that has come to be referred to as the "sequential geography methodology." Using this methodology, CMS looked to larger and larger geography areas until it

[2]CMS uses Geographic wage areas to establish a wage-index for each hospital for purposes of calculating prospective payments for inpatient care. *Id.*

identified three or more hospitals with base year PRAs to average into a mean:

> If there are less than three teaching hospitals in the same geographic wage area, we include all hospitals in contiguous wage areas. If we continue to have fewer than three hospitals for this calculation, we use the statewide average [. . . Where] there are fewer than three teaching hospitals with teaching programs in the entire state, we calculated a weighted average among all hospitals with teaching programs in contiguous states.

Pls.' Attach. U.

In 1997, the Secretary proposed to codify the sequential geography methodology in a final rule. Proposed Rule, 62 Fed. Reg. 29902, 29925 (June 2, 1997). In response to comments received on this proposed rule, HHS adopted a final rule that differs from the sequential geography methodology. Under the final rule, new teaching hospitals located in areas with less than three teaching hospitals are assigned PRAs based on either their own actual costs per resident or the "regional weighed average per resident amounts determined for each of the nine census regions established by the Bureau of Census." 62 Fed. Reg. 46004, 46034.

C. Factual Background

The Plaintiffs in this action are five not-for-profit hospitals who operate residency training program in rural family medicine. The three residency programs in question have been certified by the Accredation Council on Graduate Medical Education ("ACGME"). Although all of the Plaintiffs are located in Metropolitan Statistical Areas,[3]

[3] A Metropolitan Statistical Area is a "statistical representation" that the Office of Management and Budget ("OMB"), as well as other federal agencies, rely upon in collecting and analyzing data and setting policy. Standards for Defining

their residency programs focus on providing care to rural areas.

Providence Yakima Medical Center ("Providence") and Yakima Valley Memorial Hospital ("Yakima Valley") are located in Yakima, Washington. Until at least 2003,[4] Providence and Yakima Valley jointly operated the Central Washington Family Medicine Residency Program. Declaration of Michael Maples, July 12, 2006, ¶ 2. The program's mission is to provide a "collaborative community based program training family physicians equipped to care for rural and underserved populations." Maples Decl. ¶ 4. During their three year residency, program participants serve month long rotations in communities of 2000 to 5000 residents. Maples Decl. ¶ 5. Approximately 78% of the program's graduates go on to serve in rural areas. Maples Decl. ¶ 6. In the first year of their GME programs, Providence Yakima and Yakima Valley's allowed Medicare costs associated with graduate medical education were $ 126,125.00[5] and $116,704.00 per resident, respectively. Pls.' Attach. U at 181, 340.

St. Vincent Hospital ("St. Vincent") and Deaconess-Billings

Metropolitan and Micropolitan Statistical Areas, 65 Fed. Reg. 82228 (Dec. 27, 2000.) OMB describes a Metropolitan Statistical Area as, "an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus." *Id.*

[4]No evidence has been submitted regarding the current status of the program. The program's current status is, however, irrelevant for the purposes of the pending motions.

[5]While the Defendant disputes the validity of the first year costs claimed by the Plaintiffs, the Defendant has presented no evidence refuting them. The Plaintiffs have also provided a credible explanation as to why their costs greatly exceed those of other teaching hospitals.

Clinic Health System ("Deaconess") are located in Billings, Montana. St. Vincent and Deaconess jointly operate the Montana Family Medicine Residency Program. Declaration of Roxanne Fahrenwald, July 12, 2006. ¶ 2. The program's mission statement provides, "The Montana Family Medicine Residency Program provides the education and experience to prepare graduates to confidently practice medicine in rural communities and to provide healthcare for underserved populations in Montana." Fahrenwald Decl. Ex. 1. The residents train at both the two hospitals and nonhospital locations. Fahrenwald Decl. ¶ 7. Approximately 75-80% of the program's graduates go on to serve in rural areas. Fahrenwald Decl. ¶ 6. In the first year of their GME programs, Deaconess and St. Vincent's allowed Medicare costs associated with graduate medical education were $ 128,000.00 and $127,802.00 per resident, respectively. Pls.' Attach. U at 79, 286.

Merle West Medical Center ("Merle West") is a hospital of 100 beds located in Klamath Falls, Oregon. Merle West has operated the Cascades East Family Practice Residency program since 2001. Declaration of Robert G. Ross, July 12, 2006, ¶¶ 1-2. The program focuses on preparing doctors for practice in rural areas and approximately 80% of its graduates go on to practice medicine in areas of less than 10,000 people. Ross Decl. ¶ 5. In the first year of its GME program, Merle West's allowed Medicare costs associated with graduate medical education were $94,064.45 per resident. Pls.' Attach. U at 94.

The rural nature of the three residency programs differentiates them from other residency programs in a number of respects that make

them uniquely expensive to operate. Each of the Plaintiffs operates a single residency program. As a result, operation costs, including faculty salaries and training space, must be born entirely by the family medicine program rather than spread among multiple, diverse residency programs. The fact that family medicine generates lower fees than do other medical specialities increases this burden. In addition, family medicine programs must maintain an outpatient clinic, requiring further expenditures on the outpatient facility and its staff. Due to the programs' focus on providing care to rural areas, they also experience costs associated with community-based training, such as the cost of transporting the residents to remote areas and housing them there. Maples Decl. ¶ 7; Fahrenwald Decl. ¶ 8; Ross Decl. ¶ 6. Finally, Merle West's rural location increases its recruitment costs. Ross Decl. ¶ 6.

CMS determined PRAs for the Plaintiffs using the sequential geography methodology. In determining the PRAs for Providence Yakima and Yakima Valley, CMS relied upon "a weighted average of per resident amounts of teaching hospitals in Washington State." Answer ¶ 18. Based on this comparison, CMS assigned Providence Yakima a PRA of $65,829.71 and Yakima Valley a PRA of $65,800.65. Pls.' Attach. U at 179; Def.'s Resp. To Pls.' Statement of Facts In Support of Mot. Summ. J. ("Ct. Rec. 90") at 14-15. The geographic wage index for the Yakima Valley was 0.9541 in 1995.[6] Changes to the Hospital Inpatient

[6]Although it is unclear why the Plaintiffs cite geographic wage index figures for 1995, as opposed to other years, the Court believes that the particular geographic wage index in any given year is not the issue. The 1995 figures demonstrate that there

Prospective Payment Systems and Fiscal Year 1995 Rates, 59 Fed. Reg. 45330 (Sept. 1, 1994). The geographic wage index for other urban areas in Washington ranged from 0.9647 for Tacoma to 1.1232 for Bellingham in 1995. Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates, 59 Fed. Reg. at 45443.

In determining the PRAs for St. Vincent and Deaconess, CMS relied upon "a weighted average of per resident amounts of teaching hospitals in contiguous states." Answer ¶ 18. Based on this comparison, CMS assigned Deaconess a PRA of $57,341.45 and St. Vincent's a PRA of $57,434.69. Pls.' U at 56. In comparing St. Vincent and Deaconess to "teaching hospitals in contiguous states," CMS based St. Vincent and Deaconess' PRAs on the PRAs of fifteen acute care and one inpatient psychiatric facility, located in Idaho, North Dakota, South Dakota, and Wyoming. Pls.' Attach. U at 56-59.

In determining the PRA for Merle West, CMS relied upon "the weighted average of per resident amounts of teaching hospitals in Oregon, all of which were located within Portland Oregon Metropolitan Statistical Area." Answer ¶ 18. Based on this comparison, CMS assigned Merle West a PRA of $69,975.30. Ct. Rec. 90 at 13. During the relevant time period, Klamath Falls was considered part of the rural Oregon Metropolitan Statistical Area. Declaration of Sanford E. Pitler, June 22, 2006, Ex. 1. The geographic wage index for rural Oregon was 0.9227 in 1995. Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates, 59 Fed. Reg.

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was a considerable disparity between the geographic wage index in the Plaintiffs' locations and the geographic wage index figures in the locations to which the Plaintiffs were compared.

at 45444. The geographic wage index for Portland Oregon was 1.1181 in 1995. Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates, 59 Fed. Reg. at 45442.

D. Procedural History of the Present Action

In 2003, the Plaintiffs filed a petition for Expedited Judicial Review ("EJR") with the Provider Reimbursement Review Board ("PRRB"). The PRRB granted the petition and the Plaintiffs filed suit in this Court, challenging both 42 C.F.R. § 413.86(e)(4)(i)(B) on its face and the sequential geography methodology as applied to the Plaintiffs.

The Secretary filed a motion to dismiss the Plaintiffs' challenge to the sequential geography methodology. In May 2004, this Court granted the Secretary's motion in part and denied it in part, ultimately remanding the Plaintiffs' as-applied challenge to the PRRB.

On May 3, 2005, the PRRB accepted jurisdiction over the Plaintiffs' as-applied challenge, then granted their petition for EJR and closed the file, effectively sending the matter back to this Court for review.

DISCUSSION

I. JURISDICTION

This Court has subject matter jurisdiction over the Plaintiffs' claims pursuant to 28 U.S.C. § 1331. The Plaintiffs allege that the Department has taken actions inconsistent with the Administrative Procedure Act, 5 U.S.C. §§ 551 et seq., and Title VIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq. In addition, the Medicare statute specifically provides that the federal district courts have jurisdiction over legal challenges to the acts of the Department's

fiscal intermediaries. 42 U.S.C. § 1395oo(f)(1).

II. LEGAL STANDARD

A moving party is entitled to summary judgment when there are no genuine issues of material fact in dispute and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265, 273-74 (1986). "A material issue of fact is one that affects the outcome of the litigation and requires a trial to resolve the parties' differing versions of the truth." *S.E.C. v. Seaboard Corp.*, 677 F.2d 1301, 1306 (9th Cir. 1982).

Initially, the party moving for summary judgment bears the burden of showing that there are no issues of material fact for trial. *Celotex*, 477 U.S. at 323, 106 S. Ct. at 2553, 91 L. Ed. 2d at 274. Where the moving party does not bear the burden of proof at trial, it may satisfy this burden by pointing out that there is insufficient evidence to support the claims of the nonmoving party. *Id.* at 325; 106 S. Ct. at 2554; 91 L. Ed. 2d at 275.

If the moving party satisfies its burden, the burden then shifts to the nonmoving party to show that there is an issue of material fact for trial. Fed. R. Civ. P. 56(e), *Celotex*, 477 U.S. at 324; 106 S. Ct. at 2553; 91 L. Ed. 2d at 275. There is no issue for trial "unless there is sufficient evidence favoring the non-moving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249, 106 S. Ct. 2505, 2511, 91 L. Ed. 2d 202, 212 (1986). Conclusory allegations alone will not suffice to create an issue of material fact. *Hansen v. United States*, 7 F.3d 137, 138 (9th

Cir. 1993). Rather, the non-moving party must present admissible evidence showing there is a genuine issue for trial. Fed. R Civ. P. 56(e); *Brinson v. Linda Rose Joint Venture*, 53 F.3d 1044, 1049 (9th Cir. 1995).

III. CHALLENGES TO THE 1989 REGULATION

The Plaintiffs raise two challenges to the 1989 regulation. First, the Plaintiffs argue that the 1989 regulation was inconsistent with Congress' clear intent in enacting the 1986 statute and therefore not in accordance with the law. Second, the Plaintiffs argue that the 1989 regulation was arbitrary and capricious.

A. Accordance with the Law: Chevron Review

Judicial review of agency interpretations is governed by a two-part test, originally articulated by the Supreme Court in *Chevron v. Natural Resources Defense Council*. First, the Court attempts to determine the intent of Congress in enacting the statute using traditional tools of statutory construction. *Chevron*, 467 U.S. 837, 842, 104 S. Ct. 2778, 2781-82, 81 L. Ed. 2d 694, 702-03 (1984). If Congress's intent is clear, their intent governs. If, however, Congress's intent is ambiguous, the Court must defer to the agency's interpretation of the statute as long as it is reasonable. *Id.*

The Plaintiffs do not challenge the geography methodology applied to the majority of hospitals that established GME programs after 1984. Rather, the Plaintiffs challenge only that portion of the regulation that requires CMS to contact its Central Office when determining the PRA for a hospital in an area with less than three teaching hospitals. The Plaintiffs argue that this feature of the regulation is contrary

to both the plain language and the purpose of the governing statute. The Defendants argue that the statute is ambiguous and HHS's interpretation is therefore entitled to deference under *Chevron*.

1. Chevron step one: the statute is ambiguous

Applying the traditional tools of statutory construction, the 1986 statute is ambiguous regarding the Secretary's responsibility to establish PRAs for post-1984 GME programs.

The plain language of the 1986 statute relies on the ambiguous term "comparable programs." The statute provides:

> (F) Treatment of certain hospitals.-- In the case of a hospital that did not have an approved medical residency training program [. . .] for a cost reporting period beginning during fiscal year 1984, the Secretary shall, for the first such period for which it has such a residency training program and is participating under this subchapter, provide for such approved FTE resident amounts as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs.

42 U.S.C. § 1395ww(h)(2). The parties agree that the term "comparable programs" governs the Secretary's obligation to provide PRAs for hospitals that did not have GME programs before 1984. However, Congress did not suggest any criteria with which to determine when two programs may be considered "comparable." As the Defendant has observed, "the phrase 'comparable programs' is inherently ambiguous and begs the question of what is comparable." Mem. of Law in Supp. of Def.'s Mot. for Summ. J. ("Ct. Rec. 79") at 10. The extensive debate the parties have engaged in over the course of the present litigation regarding what is "comparable" illustrates that, standing alone, the term "comparable programs" provides the Secretary with little guidance.

Related provisions of the Medicare statutory scheme provide no further guidance. In an effort to negate the ambiguity of the phrase "comparable programs," the Plaintiffs point to two terms in the Medicare statutory scheme that they believe illustrate a clear intent on the part of Congress. The first provision cited by the Plaintiffs is the requirement that CMS set PRAs for hospitals that did have GME programs in 1984 based on the hospitals' own cost levels in the base year. 42 U.S.C. § 1395ww(h)(2)(F). This provision, the Plaintiffs suggest, indicates that Congress wanted the Secretary to consider hospitals' own particular costs in setting the PRA.

This observation fails to clarify Congress' intent in requiring the Secretary to rely on "comparable programs." While the statute expressly requires consideration of the hospitals' own costs for those that established GME programs prior to 1984, it makes no such requirement for hospitals that established programs after 1984. In using the term "comparable programs" Congress clearly intended the Secretary to rely on programs that were "like" or "similar to" the hospital under consideration. The point of contention between the parties, and the ambiguity driving this lawsuit, is how and in what ways the "comparable programs" should be similar to the hospital for which a PRA is being determined.

The second provision cited by Plaintiffs is COBRA 1985 §9202(a)(I). This section provides, "except as explicitly authorized, the Secretary is not authorized to limit the rate of increase on allowable costs of approved medical education activities." Consideration of this provision also fails to advance the present

analysis, however, because the entirety of Section 1395ww provides the "explicit authorization to limit allowable costs" for GMEs referred to in Section 9202.

2. Chevron step two: the agency's interpretation is reasonable

Where Congress' intent in enacting a statute is ambiguous, a reviewing court must defer to the agency's interpretation of the statute unless it is "contrary to clear congressional intent or frustrates the policy Congress sought to implement." *Schneider*, 450 F.3d at 960. To be upheld, an agency's construction of the statute need only be a permissible interpretation: it need not be the only possible or even the best interpretation. *Id.*

The Plaintiffs argue that the 1989 regulation frustrates the intent of Congress by treating a subset of new hospitals differently from all the others. Citing the Ninth Circuit's decision in *Schneider*, the Plaintiffs argue that, where Congress has provided a single criterion for receipt of a benefit, the agency may not impose additional requirements for receipt of the benefit on a subset of the affected group

While this argument has merit, *Schneider* is distinguishable from the present case. In *Schneider*, the Immigration and Naturalization Service ("INS") enacted a regulation requiring that immigrant doctors who had previously been denied a national interest waiver work for a period of five years before qualifying for lawful permanent resident status. In contrast, the governing statute required that immigrant doctors who had not been denied a waiver work for only three years. The Ninth Circuit held that the INS could not impose an additional

requirement on a subset of individuals governed by the statute. In the present case, HHS did not impose an additional requirement upon a subset of hospitals. Reimbursements for hospitals in areas with less than three teaching hospitals were calculated in the exactly the same manner as reimbursements for all other hospitals, by multiplying the hospital's PRA by its number of residents and its permissible Medicare expenses. A single variable in this calculation, the hospital's PRA, was determined using a different process.

The Plaintiffs contend that nothing in the statute implies that the Secretary may treat any subset of hospitals differently from the others. However, as the Defendant points out, the statute does not expressly forbid it from making such an exception. Given the absence of clear Congressional intent to the contrary, it was permissible for the Secretary to provide for the exceptional situation presented by hospitals with new GME programs located in areas where a meaningful average could be not calculated. Therefore, the challenged regulation is in accord with the law by virtue of *Chevron* deference.

B. Arbitrary and Capricious Review

A regulation may be arbitrary and capricious if, when enacting the regulation, the agency failed to consider a relevant factor, considered a factor not permitted by Congress, or failed to consider significant alternatives to the option selected. *Mt. Diablo Hosp. v. Shalala*, 3 F.3d 1226, 1231-32 (9th Cir. 1993). A regulation may also be arbitrary and capricious if it is wholly unsupported by available evidence. While *Chevron* analysis examines the agency's interpretation of the statute, arbitrary and capricious analysis focuses on the

agency's decision-making process.

The Plaintiffs argue that the 1989 regulation was arbitrary and capricious because the Secretary failed to respond to significant comments that addressed potential problems with the geography methodology. The Plaintiffs further argue that the 1989 regulation was arbitrary and capricious because the administrative record provided no basis for the Secretary's decision to treat hospitals in areas with less than three teaching hospitals differently from other hospitals.

1. Failure to respond to comments

The Defendant's alleged failure to address concerns about the geography methodology in the final 1989 rule is not dispositive for two reasons. First, none of the comments HHS received concerned the exception the 1989 regulation made for hospitals in areas with less than three teaching hospitals. As the Defendant correctly observes, the two comments cited by the Plaintiffs refer to the geography methodology applied to all hospitals with new GME programs rather than the exception the 1989 regulation made for hospitals located in areas with less than three teaching hospitals. Second, "The failure to respond to comments is grounds for reversal only if it reveals that the agency's decision was not based on a consideration of the relevant factors." *Am. Mining Congress v. EPA*, 965 F.2d 759, 771 (9th Cir. 1992); *Mt. Diablo*, 3 F.3d at 1232. As discussed above, Congress did not specify any factors that the Department should consider in defining "comparable programs." Any failure to respond to comments could not thereby illustrate failure to consider such a factor.

2. Failure to explain exception for hospitals in areas with less than three teaching hospitals

An agency's failure to explain its reasoning is sufficient grounds to remand the regulation as arbitrary and capricious. *Alvarado Cmty. Hosp. v. Shalala,* 166 F.3d 950 (9th Cir. 1999); *Beno v. Shalala*, 30 F.3d 1057, 1076 (9th Cir. 1994). As the Plaintiffs correctly observe, the administrative record provides no insight into the Defendant's decision to treat hospitals in areas with less than three teaching hospitals differently from other hospitals that established GME programs after 1984.

In defense of the 1989 regulation, the Defendant refers to his explanation for the exception in his proposed 1997 rule. However, post hoc rationalizations for agency actions will not suffice: only explanations made at the time of the rule-making may be used to defeat a charge of arbitrary and capriciousness. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 50, 103 S. Ct. 2856, 2870, 77 L. Ed. 2d 443, 462 (1983); *Gifford Pinchot Task Force v. United States Fish & Wildlife Serv.,* 378 F.3d 1059, 1073 (9th Cir. 2004).

The Defendant's argument that no explanation for the exception was necessary presents a closer question. According to the Defendant, the rationale underlying the exception,

> [. . .] was implicit in the regulation itself. It was obvious that where there were fewer than three PRAs in a hospital's geographic wage area [. . .] a fiscal intermediary would not be able to calculate a meaningful average PRA because one hospital's aberration could significantly skew the average.

The Defendant has cited no case law excepting "obvious" reasons from

an agency's duty to provide "a concise general statement of [a rule's] basis and purpose." 5 U.S.C. § 553©). However, requiring an agency to explain every single phrase of a final rule, even those phrases that went unchallenged during the notice and comment period, would impose a strenuous burden on the agency. This burden hardly seems justified in the present situation, as there can be little doubt of the reason underlying the exception for hospitals in areas with less than three teaching hospitals.

Fortunately, it is not necessary for the Court to resolve this dilemma. The portion of the regulation in question has been replaced by the 1997 rule. The only question before this Court is the legality of the sequential geography methodology itself. This methodology is so unpersuasive that it must be rejected for substantive reasons.

II. CHALLENGES TO THE SEQUENTIAL GEOGRAPHY METHODOLOGY

The Plaintiffs contend that the sequential geography methodology is both procedurally and substantively invalid. Procedurally, the Plaintiffs argue that CMS's practice of applying the sequential geography methodology to hospitals located in areas where there were less than three teaching hospitals amounted to a legislative rule that required formal rule making under Section 553 of the Administrative Procedure Act. Substantively, the Plaintiffs allege that the sequential geography methodology is arbitrary and capricious.

A. Procedural Validity: Applicability of the Notice and Comment Requirement

The Administrative Procedure Act ("APA") codifies the procedural requirements agencies must observe in conducting particular activities. The parties agree that HHS must conform to these

requirements in administering Medicare. Under Section 553 of the APA, an agency must provide public notice and an opportunity for comment, among other procedures, when it enacts a substantive rule. 5 U.S.C. § 553(b). An agency's failure to conform to the requirements of Section 553 invalidates the rule. *Linoz v. Heckler*, 800 F.2d 871, 877 (9th Cir. 1986).

In contrast, an agency may enact an interpretive rule without observing the requirements of Section 553. 5 U.S.C. § 553(b)(A). Agencies may also fill gaps in their regulations on a case-by-case basis through informal adjudications as long as proceeding in this manner does not constitute an abuse of discretion. *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294, 94 S. Ct. 1757, 1771-72, 40 L. Ed. 2d 134, 154 (1974); *SEC v. Chenery Corp.*, 332 U.S. 194, 202-03, 67 S. Ct. 1575, 1580, 91 L. Ed. 1995, 2002 (1947); *Comm. Hosp. of Monterey Peninsula v. Thompson*, 323 F.3d 782, 790 (9th Cir. 2003).

1. The sequential geography methodology was established as an interpretive rule

The Defendant argues that the sequential geography methodology was valid as an interpretive rule. Whether a rule is substantive or interpretive is a question of law courts review *de novo*. *Ward v. Shalala*, 149 F.3d at 79; *Hemp Indust. Ass'n*, 333 F.3d 1082, 1086 (9th Cir. 2003). Legislative rules "create rights, impose obligations, or effect a change in exiting law pursuant to authority delegated by Congress." *Hemp Indust.*, 333 F.3d at 1087. In contrast, interpretive rules "merely explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule." *Id.* An interpretive rule is nonbinding in the sense that it does not

foreclose alternate courses of action. *Linoz*, 800 F.2d at 877. The Ninth Circuit has adopted a useful framework to identify legislative rules. A rule is legislative:

> (1) when, in the absence of the rule, there would not be an adequate legislative basis for enforcement action;
> (2) when the agency has explicitly invoked its general legislative authority;
> (3) when the rule effectively amends a prior legislative rule.

Hemp. Indust. 333 F.3d at 1087. Applying the Ninth Circuit's *Hemp Industries* test, it is clear that the sequential geography methodology was not a substantive rule.

First, the methodology itself did not provide the necessary basis for enforcement action. The 1986 statute and HHS's 1989 regulation provided the legislative basis for determining the PRAs of all hospitals. The 1989 rule specifically provided that Medicare intermediaries should consult CMS's Central Office when asked to determine a PRA for a hospital with a post-1984 GME program located in an area with less than three teaching hospitals. This consultation is the enforcement mechanism and it is contained in the regulation.

Second, the Agency did not invoke its legislative authority in developing the sequential geography methodology. The Plaintiffs argue that CMS's reliance on the sequential geography methodology amounted to a substantive rule because the 1986 statute required the Secretary to invoke his rule-making power to change the manner in which hospitals were reimbursed for GME programs. As a result, the sequential geography methodology "established a new legal standard" for the subset of hospitals at issue in this case. These statements are correct in regard to the Agency's 1989 regulation: it did change

the manner in which Medicare reimbursed hospitals for GME programs. It likewise provided a new legal standard for determining PRAs for all post-1984 GME programs except those located in more isolated areas. However, the Secretary never promulgated a rule codifying the sequential geography methodology. Rather, as the Plaintiffs have admitted, the sequential geography methodology was administered on an ad hoc basis. (Ct. Rec. 86 at 12.)

Third, the sequential geography methodology amended neither the 1986 statute nor the 1989 regulation. The 1989 regulation carved out an exception for hospitals located in areas with less than three teaching hospitals. It did not articulate a standard to apply to these hospitals. Instead, the challenged methodology filled a gap that the Agency had left open when it enacted the 1989 regulation.

The Plaintiffs argue that the sequential geography methodology constituted a substantive rule because CMS applied it, without exception, to all similarly situated hospitals. However, consistent application of the challenged methodology is not determinative because the methodology was apparently not binding upon either the Secretary or the PRRB. If the PRRB had reviewed any of the PRAs determined using the sequential geography methodology, it would not have been bound to respect the agency's use of that methodology. (Ct. Rec. 79 at 19.) Furthermore, the Secretary retained discretion to deviate from the methodology. It seems the Agency decided to codify the methodology in a final rule as soon as it realized the methodology had, through repeated application, become the agency's policy. This is exactly what agencies should do when they realize that one of their

practices has evolved into a policy.

2. The sequential geography methodology as the result of informal adjudication

In the alternative, the Defendant argues that the sequential geography methodology was not a rule at all, but rather an outcome, developed on a case-by-case basis, of several informal adjudications. (Ct. Rec. 79 at 17-18.) The Defendant observes that the sequential geography methodology was applied to only six to twelve of the over one thousand hospitals that receive reimbursement from Medicare for GME programs. Ex. 1 to Statement of Material Facts in Support of Def.'s Mot. for Summ. J. at 17.

The Plaintiffs have not addressed the argument that the sequential geography methodology developed through a series of informal adjudications. Nor have they, accordingly, suggested that the Secretary abused his discretion in electing to assign PRAs for hospitals in isolated areas through informal adjudications rather than a rule-making. The Court has found no reason to believe that the Secretary's reliance on informal adjudication in this context is so unfair as to constitute an abuse of discretion under *SEC v. Chenery Corporation* and *NLRB v. Bell Aerospace Company.*

The sequential geography methodology is properly characterized as the result of a series of informal adjudications. The methodology was developed on a case-by-case basis, a process more consistent with informal adjudication than a predetermined interpretive rule. Furthermore, as the Plaintiffs have argued, the Medicare statute requires the Secretary to publish interpretive rules in the Federal Register on a periodic basis. 42 U.S.C. 1395hh©). Given that the

Secretary did not publish such a notice regarding the sequential geography methodology, the logical inference is that the methodology evolved through informal adjudications. However, whether the sequential geography method is considered an interpretive rule or an informal adjudication ultimately makes no difference. Neither requires compliance with the procedures of Section 553 and, under the present facts, both receive the same level of deference.

B. Level of Deference

Agency decisions that lack the force of law are entitled to deference only to the extent that they have the power to persuade. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). Under *Skidmore* deference, the degree of deference due an agency's decision,

> will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade if lacking the power to control.

Id. The sequential geography methodology lacked the force of law and is thus not entitled to *Chevron* deference. Nor is the Agency's use of this methodology entitled to deference under *Auer v. Robbins*, 519 U.S. 452, 117 S. Ct. 905, 137 L. Ed. 2d 79 (1997).

1. The sequential geography methodology is not entitled to Chevron deference

Neither an interpretive rule nor an informal adjudication is entitled to Chevron deference. *Christensen v. Harris County*, 529 U.S. 576, 587, 120 S. Ct. 1655, 1662-62, 146 L. Ed. 2d 621, 631 (2000); *Comm. Hospital*, 323 F.3d at 791. As the Supreme Court has explained, "Interpretations such as those in opinion letters- like interpretations contained in policy statements, agency manuals, and

enforcement guidelines, all of which lack the force of law- do not warrant *Chevron*-style deference." *Id.* An agency act lacks the force of law when the act has no precedential value for subsequent parties. *High Sierra Hiker's Ass'n v. Blackwell*, 390 F.3d 630, 648 (9th Cir. 2004). Even Agency rules promulgated through notice and comment rule-making will be denied *Chevron* deference if they do not constitute binding precedent." *Hall v. EPA*, 273 F.3d 1146, 1155-56 (9th Cir. 2001)(citing *United States v. Mead Corp.*, 533 U.S. 218, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001)).

In the present case, the Defendant has made it very clear that the sequential geography methodology was applied on a case-by-case basis and bound neither the PRRB nor the Secretary. Def.'s Mem. Of Law in Supp. Of Def.'s Mot. For Summ. J. ("Ct. Rec. 79") at 19. It thus lacked the force of law and is not entitled to *Chevron* deference.

2. The sequential geography methodology is not entitled to *Auer* deference

The Defendants argue that, rather than applying *Skidmore* deference, the Court should accord great deference to the Agency's use of the sequential geography methodology under *Auer v. Robbins*. In *Auer*, the Supreme Court held that an agency's interpretation of its own rule is entitled to substantial deference. 519 U.S. at 462-463; 117 S. Ct. at 912, 137 L. Ed. 2d at 91. However, "*Auer* deference is warranted only where the regulation is ambiguous." *Christensen*, 529 U.S. at 588, 120 S. Ct. at 1663, 146 L. Ed. 2d at 632. Where the regulation fails to address an issue, rather than addressing it in an ambiguous manner, *Auer* deference is inappropriate. *Id.* Moreover, *Auer* deference is only applicable to an agency's interpretation of

regulatory language that originated with the agency, as opposed to statutory language developed by Congress. *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 915, 163 L. Ed. 2d 748, 767 (2006).

In this case, the regulation is not ambiguous. The 1989 regulation specifies the criteria CMS must use to determine PRAs for the hospitals who established GME programs after 1984. 42 C.F.R. 413.86(e)(4)(i)(B)(1989). The regulation then makes an exception for hospitals located in areas with less than three teaching hospitals, providing that the Central Office will determine the appropriate PRAs for these hospitals. *Id.* There is nothing ambiguous about this exception; it is clear what intermediaries must do and who will decide PRAs for the affected hospitals.

The regulation wholly fails to indicate what criteria the Central Office will use in making this determination. In fact, the gap created by this reservation of discretion to the Central Office is far larger than that in *Christensen v. Harris County*. "Since the regulation gives no indication how to decide the issue, the [Secretary's] efforts to decide it now cannot be considered an interpretation of the regulation." *Gonzales v. Oregon*, 126 S. Ct. at 915-916; 163 L. Ed. 2d at 767. HHS accordingly utilized the sequential geography methodology as a way of implementing the statutory term "comparable programs," rather than the standards specified in the 1989 regulation.

In reserving the question of how to determine PRAs for hospitals in isolated areas, the Secretary retained considerable discretion for the Central Office. Having retained discretion to interpret the

wording of a statute on a case-by-case basis through informal adjudications, with none of the procedural checks set forth in the APA and without even publishing an interpretive rule to give potentially affected parties notice of how the Agency will decide these issues, the Agency cannot then claim that its informal decisions "represent the considered view of the agency." *Skidmore* deference is appropriate to the present inquiry.

C. Application of *Skidmore* Deference

Applying the factors articulated in *Skidmore*, the Court finds that the sequential geography methodology is unpersuasive. First, the record does not show that HHS developed the methodology after a thorough consideration of the relevant facts and law. In response to interrogatories, the Defendant indicated that only a single individual, a March Hartstein, could be located who remembered applying the policy. Pls.' Attach. T at 13. According to Hartstein,

> the methodology was reasonable because: (1) it was consistent with the general policy reflected in the prospective payment system that, due to salary differentials across geographic areas, reimbursement should be tied to geographic area; (2) it had been used by the Division of Hospital Payment Policy for a number of years [prior to Hartstein's involvement] and (3) to Mr. Hartstein's knowledge, it had not been challenged by any provider.

Id. Hartstein's recollection fails to explain the basis for HHS's initial application of the methodology. Moreover, it does not appear that the Defendant considered the position of hospitals located in areas with less than three teaching hospitals. The Defendant was quick to recognize the unique position of these hospitals when it carved out an exception in the 1989 regulation to allow for individualized determination of their PRAs by the Central Office.

Yet, when required to calculate the PRA for such a hospital, it did not take this unique position into account.

Second, to the extent that it is possible to identify the reasoning underlying the methodology, this reasoning is invalid. In adopting the 1989 regulation, HHS determined that hospitals in the same geographic wage area could be considered comparable because salary is one of the primary costs of GME programs. This rationale refutes the idea that hospitals located in different geographic wage areas are comparable. Nothing in the 1989 regulation suggests that contiguous wage areas are necessarily similar. The facts before the Court demonstrate that the opposite is true: Yakima and Bellingham might be in contiguous wages areas, but 0.9541 does not and never will be equal to 1.1232, particularly from the perspective of one paying wages based on those numbers. It seems that HHS was more concerned with mechanically applying a readily available formula than with ensuring that the PRAs of more isolated hospitals were based on those of truly "comparable" facilities.

The inconsistent reasoning described above further demonstrates that the sequential geography methodology was inconsistent with HHS's earlier pronouncements. The Defendant argues that the sequential geography methodology was a logical extension of the methodology applied to other hospitals. However, as previously stated, the assumption that hospitals located within the same geographic wage area are comparable refutes, rather than supports, the idea that hospitals located in different geographic wage areas are comparable.

The challenged methodology was likewise inconsistent with the

1989 regulation because it resulted in PRAs that bore no relationship to the Plaintiffs' actual costs. When HHS published its proposal for the 1989 rule, it indicated that its goals in adopting the geographic methodology for hospitals with GME programs established after 1984 included establishing PRAs for these newer GME programs that bore "some relationship to the actual cost of the program." 53 Fed. Reg. 36595. The Plaintiffs have submitted evidence illustrating disparities of between $24,089.15 (Merle West) and $70,658.55 (Deaconess) between their actual first year costs per resident and the PRAs assigned to them by CMS.

Finally, application of the sequential geography methodology produced results inconsistent with the goal of both the governing statute and the goal of the 1989 regulation: reliance on the PRAs of "comparable" hospitals. The evidence submitted by the Plaintiffs shows that the residency programs at issue are uniquely expensive to operate. At the very least, it is clear that the Plaintiffs experience and must deal with costs very differently from hospitals in urban areas who operate multiple residency training programs.[7] Yet, CMS relied upon the PRAs of just such urban hospitals in setting the Plaintiffs' PRAs.

CONCLUSION

The Court holds that the Department's reliance on the sequential

[7]The Defendant argues that comparing the Plaintiffs to hospitals in urban areas actually benefitted the Plaintiffs because the PRAs of urban areas tend to be greater than those of rural areas. While this argument has some merit, it does not negate the fact that the Plaintiff hospitals experience costs very differently from their comparators.

geography methodology to determine PRAs for hospitals that established GME programs after 1984 located in areas with less than three teaching hospitals was arbitrary and capricious. As such, it was unlawful and must be set aside. Accordingly,

IT IS HEREBY ORDERED:

1. The Plaintiffs' Motion for Summary Judgment, **Ct. Rec. 82**, is **GRANTED.**

2. The Defendant's Motion for Summary Judgment, **Ct. Rec. 79**, is **DENIED.**

3. The Plaintiffs shall submit a supplemental brief, not to exceed **fifteen (15) pages** in length, no later than **5:00 p.m.** on **April 23, 2007**, addressing the question: "In view of the Court's ruling on summary judgment, what is the proper remedy in this case?"

4. The Defendant shall file his response to the supplemental briefing, if any, no later than **5:00 p.m.** on **May 8, 2007.**

5. The Plaintiffs shall file their reply, if any, no later than **5:00 p.m.** on **May 15, 2007.**

IT IS SO ORDERED. The District Court Executive is hereby directed to enter this order and furnish copies to counsel.

DATED this 29th day of March, 2007.

s/ Fred Van Sickle
Fred Van Sickle
United States District Judge